Case: 4:12-cv-02266-CDP Doc. #: 1-1 Filed: 12/07/12 Page: 1 of 26 PageID #: 7



Judge or Division:

IN THE 21ST JUDICIAL CIRCUIT COURT, ST. LOUIS COUNTY, MISSOURI

Case Number: 12SL-CC04020

BARBARA W WALLACE				
Plaintiff/Petitioner:	Plaintiff's/Petitioner's Attorney/Address			
MARJIE LEVY	RICHARD S CORNFELD			
	1010 MARKET STREET			
	STE 1605			
VS.	ST LOUIS, MO 63101 Court Address:			
Defendant/Respondent:	ST LOUIS COUNTY COURT BUILDING			
PFIZER INC	7900 CARONDELET AVE			
Nature of Suit: CC Other Tort	CLAYTON, MO 63105	(Data Pila 04a)		
		(Date File Stamp)		
	immons in Civil Case			
The State of Missouri to: PFIZER INC Alias:	2.100			
120 C OFFICE AT AND	C	7		
SERVE RA CT CORPORATION SYSTEM ST LOUIS, MO 63105	701 B			
S1 E0015, MO 03105	Con B			
COURT SEAL OF You are summone	d to appear before this court and to file your pleading to	the petition, a copy of		
which is attached, and	to serve a copy of your pleading upon the attorney for Pl	aintiff/Petitioner at the		
	in 30 days after receiving this summons, exclusive of the comment by default may be taken against a fact the collision			
	ment by default may be taken against you for the relief	manded in the petition.		
29-OCT-2012 Date	Clerk	taney		
CT LOUIC COUNTY	Clerk			
Further Information: JMC				
Sheriff's or Server's Return				
Note to serving officer: Summons should be returned to the court within thirty days after the date of issue.				
I certify that I have served the above summons by: (check one)				
delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.				
leaving a copy of the summons and a copy of the pe	tition at the dwelling place or usual abode of the Defendant/	Respondent with		
(for sowing on a corporation) delivering a converte	nereby Cently that on this date "Norty der	the age of 15 years.		
(for service on a corporation) delivering a copy of the summons and a copy of the petition to the summons and a copy of the petition to the summons and a copy of the petition to the summons and a copy of the petition to the summons and a copy of the petition to the peti				
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otner cie	elivering a copy to CT CORP THE COM	2/00 / 1 / 1 / 1 / 1 / 1 / 1 / 1 / 1 / 1		
Served at	ne registered agent of the defendant, by le	aving (address)		
in (County/Cit Co	pry with, Bullove, Z. King, Meehan, (date) at	<u></u>		
		The state of the s		
Printed Name of Sheriff or Server	m Buckles by Sindature of Sheri	ff or Server		
Must be sworn before a n	neriff, St. Louis County an authorized officer. Sher	iff		
Subscribed and sworn to be (Seal)	efore me on(date). 🖒		
My commission expires:		• • • • • • • • • • • • • • • • • • • •		
	Date N	lotary Public		
Sheriff's Fees, if applicable				
Summons \$ Non Est \$		6		
Sheriff's Deputy Salary				
Supplemental Surcharge \$ 10.00	i o			
Mileage	iles @ \$ per mile)			
	e served on each Defendant/Respondent. For methods of ser	vice on all classes of		
suits, see Supreme Court Rule 54.				

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IN THE 21ST JUDICIAL CIRCUIT COURT, ST. LOUIS COUNTY, MISSOURI

			_
Judge or Division:		Case Number: 12SL-CC04020	
BARBARA W WALLACE			
Plaintiff/Petitioner:		Plaintiff's/Petitioner's Attorney/Address	
MARJIE LEVY		RICHARD S CORNFELD	i
		1010 MARKET STREET	
		STE 1605	
	VS	ST LOUIS, MO 63101 Court Address:	
Defendant/Respondent:		ST LOUIS COUNTY COURT BUILDING	
PFIZER INC		7900 CARONDELET AVE	
Nature of Suit: CC Other Tort		CLAYTON, MO 63105	(Date File Stamp)
CC Other Tort		Language in Civil Cogo	<u> </u>
		Summons in Civil Case	
The State of Missouri t			
120 S CENTRAL AVE	Alias:		
SERVE RA CT CORPORATIO	N SYSTEM		
ST LOUIS, MO 63105			
You are summoned to appear before this court and to file your pleading to the petition, a copy of which is attached, and to serve a copy of your pleading upon the attorney for Plaintiff/Petitioner at the above address all within 30 days after receiving this summons, exclusive of the day of service. If you file your pleading, judgment by default may be taken against you for the relief semanded in the petition.			
No. of the last of	29-OCT-2012 Date	Clerk	John J. C. Comp.
ST. LOUIS COUNTY	Further Information: JMC		
		Sheriff's or Server's Return	
Note to serving officer:	Summons should be returne	ed to the court within thirty days after the date of issue.	
	the above summons by: (c		
-		1 the Defendant/Deanendant	

	JMC	
	Sheriff's or Server's Return	
Note to serving officer: S	Summons should be returned to the court within thirty days after	the date of issue.
	the above summons by: (check one)	
	e summons and a copy of the petition to the Defendant/Respond	lent.
leaving a copy of the	ummons and a copy of the petition at the dwelling place or usua	al abode of the Defendant/Respondent with
leaving a copy of the s	a person of the Defendant's/l	Respondent's family over the age of 15 years.
(for service on a corpo	ration) delivering a copy of the summons and a copy of the peti	
	(name)	
	(nano)	
Served at		
in .	(County/City of St. Louis), MO, on	(date) at(tim
Printed Nam	ne of Sheriff or Server	Signature of Sheriff or Server
	Must be sworn before a notary public if not served by an	authorized officer:
(Seal)	Subscribed and sworn to before me on	
	My commission expires:	Notary Public
		Trough Transfer
Sheriff's Fees, if applicable Summons	8	
Non Est		•
Sheriff's Deputy Salary	<u></u>	
Supplemental Surcharge	\$ 10.00	
Mileage	(miles @ \$ per mile)	
Total	B	1 . T
A copy of the summons and	i a copy of the petition must be served on each Defendant/Resp	ondent. For methods of service on all classes of
suits, see Supreme Court R	ule 54.	

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IN THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS STATE OF MISSOURI

MARJIE LEVY,

Plaintiff,

v.

PFIZER INC.,

Serve: CT Corporation System 120 South Central Avenue

Clayton, MO 63105

Defendant.

Case No.: PSL-CCOHONC

Division:



PLAINTIFF'S CLASS ACTION PETITION

Plaintiff Marjie Levy, on behalf of herself and all others similarly situated, brings this action against Defendant Pfizer Inc. ("Defendant") and for her Petition, based upon personal knowledge as to her own acts and upon information and belief (based on the investigation of counsel) as to all other matters, alleges as follows:

INTRODUCTION

- 1. With this lawsuit, Plaintiff challenges Defendant's unconscionable, unfair, deceptive, unethical and illegal practice of misleading consumers into throwing away their Advil medication as soon as its so-called "expiration date" has passed, even though Defendant knows, or should know, that if stored properly it can and does remain chemically stable, safe and effective long after that date.
- 2. On behalf of herself and similarly situated Missouri consumers, Plaintiff seeks damages and equitable relief, including an order compelling Defendant to provide consumers with accurate information regarding the meaning of the so-called "expiration dates" printed on

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the packages of Advil; to provide accurate information as to when Advil is no longer safe and effective; and to tell consumers how to store it extend its useful life.

- 3. Advil is an Over-the-Counter" ("OTC") medication, available without a physician's prescription for minor, temporary conditions like headaches, menstrual pain, minor pain of arthritis, muscle pain, and aches and pains of the common cold. As required by regulations promulgated by the United States Food & Drug Administration ("FDA"), every container of Advil displays a date, called an "expiration date." That date does not mean that the medication is unsafe or ineffective once the date has passed.
- 4. FDA requires a manufacturer like Defendant to conduct testing to assure the stability of its OTC drug products only up until a date of the manufacturer's own choosing, but not thereafter. That date becomes the so-called "expiration date." Upon information and belief, Defendant has never conducted testing that would show that, at any time after the "expiration date," Advil is not stable, safe or effective. Thus, Defendant has never told consumers the full period during which Advil will remain safe and effective.
- 5. In fact, Defendant knows, or should know, that medications such as Advil remain safe and effective long after its so-called "expiration date." That is the conclusion to cite two examples of Harvard Medical School and Johns Hopkins Medical School, a conclusion based in part on testing by the federal government.
- 6. Nevertheless, on its web sites and elsewhere, Defendant illegally deceives consumers into throwing away Advil as soon as the "expiration date" has passed by misrepresenting supposedly "expired" medications as unsafe and ineffective.
- 7. The purpose behind this scheme is to increase Defendant's sales and profits because consumers have to purchase replacement medications for those they have thrown out.

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- 8. Defendant carries out this illegal scheme in a number of ways, both individually and collectively with other members of its industry. For example, Defendant not only makes affirmative misrepresentations about the need to get rid of supposedly "expired" medications, but it fails to provide to consumers information that it knows, or should know, to be true and that would make the so-called "expiration dates" not misleading, including that it chooses the "expiration date" based on its own marketing considerations, not scientific reasons, and that the "expiration date" does not indicate how long the product is actually "good" or safe to use. Nor, among other omissions, does Defendant state that consumers may continue to take the product as long as it works as expected and should discard it only if it loses effectiveness.
- 9. Defendant conspires with other manufacturers of OTC medications to carry out this scheme by promoting disposal of supposedly expired medications through their industry associations, the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Consumer Healthcare Products Association ("CHPA"). These associations engage in supposed public service campaigns to mislead consumers into believing that it is socially responsible to throw away medications that have passed their so-called "expiration dates."
- 10. By its actions in deceiving consumers into getting rid of medications that are still "good," Defendant has violated the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010 *et seq.* ("MMPA"), and engaged in an illegal civil conspiracy, causing injury to Plaintiff and the other members of the class.

VENUE AND JURISDICTION

11. The Circuit Court of St. Louis County has subject matter jurisdiction over this action because the actions complained of regarding Plaintiff took place in St. Louis County.

V.A.M.S. § 407.025.1.

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12. This court has personal jurisdiction over Defendant because it regularly conducts business in St. Louis County.

13. Venue is proper in the Circuit Court of St. Louis County because the cause of action arose in St. Louis County. V.A.M.S. § 407.025.1.

PARTIES

- 14. Plaintiff Marjie Levy is, at all times relevant hereto, a Missouri citizen residing in St. Louis County who purchased Advil and discarded it after the expiration date even though there was medication remaining.
- 15. Defendant Pfizer Inc. is a Delaware corporation with a principal place of business at 225 E. 42nd Street, New York, NY 10017. It advertises and sells throughout the United States, including Missouri, "many of the world's best-known OTC, or self-medications," including Advil, which it states is "The #1 Selling Pain Reliever" among OTC brands. Defendant claims to be "focused ... on operating with transparency in everything we do" Defendant does substantial business within the State of Missouri through its sale of Advil within the State.

FACTUAL BACKGROUND

- A. The so-called "expiration date" mandated by government regulations does not indicate how long the product remains stable, safe and effective
- 16. FDA regulations require that manufacturers of OTC medications include a date, called an "expiration date," on the immediate container as well as the outer package of the product. 21 C.F.R. §§ 211.137(b), 201.17.
- 17. Manufacturers of OTC medications are required to have a written testing program designed to assess the stability characteristics of their drug product in its original packaging and

¹ Pfizer, Inc. Form 10-K for 2011 at 1; http://www.advil.com/ (accessed October 11, 2012).

² http://www.pfizer.com/about/ (accessed October 11, 2012).

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to use the results of such testing in determining the so-called "expiration date" of the product. 21 C.F.R. § 211.166. But nothing in the regulations determines the precise shelf life that the manufacturers must test; the "expiration date" is therefore subject to the manufacturer's unilateral decision.

- 18. Nor do the regulations prevent manufacturers from conducting tests to determine how long the products remain stable. However, on information and belief, Defendant regularly tests Advil only up to the "expiration date" it chooses, but not beyond it.
- 19. Moreover, on information and belief, Defendant tests Advil only in its sealed, original packaging under conditions likely to be encountered during shipping and storage at retail. It does not test Advil under conditions of storage in a typical consumer's home, such as in an intermittently hot and humid bathroom after the bottle's seal has been broken and the bottle has been opened. The regulations do not prohibit such testing.
- 20. Nor does federal law govern when it is permissible for a consumer to take an OTC medication. The regulations control only the period when it can be sold.
- 21. Thus, an "expiration date" is simply the manufacturer's representation that the medication will remain stable in the original sealed packaging until that date, but it says nothing about whether the medication will or will not remain stable beyond that date.
 - B. As Defendant knows or should know, Advil remains stable, safe and effective long after the "expiration date" on its labels
- 22. Defendant knows, or should know, that OTC medications like Advil remain stable and are safe and effective for consumers to use years after their "expiration dates."
- 23. Beginning in the 1980s, the FDA conducted a program at the request of the United States military, called the "Shelf Life Extension Program" or "SLEP." The program was designed to keep the military from having to discard hundreds of millions of dollars' worth of

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supposedly expired stockpiled medicines. Under it, the FDA tested the stability of more than 100 prescription and OTC drugs.

- 24. According to findings that, as described below, were later relied upon by physicians and scientists, 90% of the medications tested "were safe and effective far past their original expiration date, at least one for 15 years past it." Laurie Cohen, *Many Medicines Are Potent Years Past Their Expiration Dates*, Wall Street Journal at A-1 (March 29, 2000).
- 25. As a result of this program, the military stopped discarding supposedly "expired" medication and, its savings were huge. During just five years in the 1990s, the program resulted in net savings of approximately \$260 million from drugs that did not need to be destroyed and replaced. *Id.*
- 26. Francis Flaherty, the FDA's former director of the testing program, concluded "that "expiration dates" put on by manufacturers typically have no bearing on whether a drug is usable for longer." *Id.* According to Mr. Flaherty, "[m]anufacturers put expiration dates on for marketing, rather than scientific reasons." He went on: "It's not profitable for them to have products on a shelf for 10 years. They want turnover." *Id.* (quoting Francis Flaherty, former director of the SLEP testing program).
- 27. The study found "that expiration dates put on by manufacturers typically have no bearing on whether a drug is usable for longer.... '[M]anufacturers put expiration dates on for marketing, rather than scientific reasons'.... 'It's not profitable for them to have products on a shelf for 10 years. They want turnover." *Id.*
- 28. The study also found that, but for exceptions like nitroglycerin, insulin and some liquid antibiotics none of them subject to Plaintiff's claims herein "[m]ost drugs degrade very

slowly.... In all likelihood, a product at home can be kept for many years, especially if it's in the refrigerator." *Id.* (quoting Joel Davis, former FDA expiration-date compliance chief).

- 29. FDA found that most drugs have a 36-month "expiration date" from the date of manufacturing, a period that is based on the companies' commercial distribution practices and marketing strategies because they make money by turning over their product. *History of the U.S. Food and Drug Administration*, Interviewee: Francis J. Flaherty, June 14, 2000, at 30. Manufacturers would use a shorter date if they could "get away with it." *Id.*
- 30. FDA also found that drugs degrade only very slowly. They do so "on a curve; in most cases a long, slow curve." *Id.* at 31.
- 31. The drug companies were well-aware of the SLEP program and never challenged its findings despite losing millions of dollars in sales as a result of it. *Id.* at 36. The SLEP program prevented the drug companies from "ripping off" the government by selling products with unrealistically short expiration dates. *Id.* at 36.
- 32. Since the SLEP program came to light, many medical authorities have relied on it and other data to come to the conclusion that supposedly "expired" drugs, especially OTC medications taken for minor, non-life-threatening conditions, need not be discarded.
- 33. On August 21, 2003, the Medscape website published an article titled, "Do Medications Really Expire?" Medscape is a website that "offers specialists, primary physicians, and other health professionals the Web's most robust and integrated medical information and educational tools." Its mission is "[t]o provide clinicians and other healthcare professionals with the most timely comprehensive and relevant clinical information to improve patient care."

³Richard Altschuler, *Do Medications Really Expire?*, http://www.medscape.com/viewarticle/460159 (accessed October 11, 2012; registration required).

⁴ http://www.medscape.com/public/about (accessed October 11, 2012).

- Relying in part on the FDA's SLEP study, the Medscape article reported that the "expiration date" on a drug label "does not mean how long the drug is actually 'good' or safe to use." According to the article, drugs past their "expiration date" are not unsafe: "[M]edical authorities uniformly say it is safe to take drugs past their expiration date -- no matter how 'expired' the drugs purportedly are." *Id.*
 - 35. The author of the Medscape article advised:

Even 10 years after the "expiration date," most drugs have a good deal of their original potency. So wisdom dictates that if your life does depend on an expired drug, and you must have 100% or so of its original strength, you should probably toss it and get a refill, in accordance with the cliché, "better safe than sorry." If your life does not depend on an expired drug – such as that for headache, hay fever, or menstrual cramps – take it and see what happens.

Id. Advil is taken for the non-life threatening condition of headache that the author listed.

- 36. The author concluded by referring to the "many billions of dollars the pharmaceutical industry bilks out of unknowing consumers every year who discard perfectly good drugs and buy new ones because they trust the industry's 'expiration date labeling.'" *Id.*
- 37. Harvard Medical School has also come to the conclusion that drugs are not ineffective simply because the "expiration date" has passed. The *Harvard Health Letter* has stated that expiration dates "serve more to protect the pharmacies and manufacturers than to tell you when your pills are no good." Thomas H. Lee, *By the Way, Doctor Are expired medications dangerous*, Harvard Health Letter (July 2003). That article stated that drugs that are past the "expiration date" are neither harmful nor ineffective:

There are two ways in which pills might "go bad." Theoretically, the chemicals in a medication could break down into something that's harmful. But cases of that actually happening are virtually unknown. There was one report of an antibiotic that had degraded into a form that was harmful to the kidneys, but that antibiotic has been changed so this danger is practically nonexistent.

The more important issue is whether pills lose their potency because they have been exposed to air, light, and moisture. Sitting in their vials in a dry, dark place

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like a medicine cabinet, most pills will stay effective for at least five years. Some medications have been shown to be stable as many as 30 years after they were made.

Id.

- 38. Similarly, the *Harvard Medical School Family Health Guide*, relying on the Medscape article discussed above and the SLEP study that the FDA did for the military, came to this conclusion: "So the "expiration date" doesn't really indicate a point at which the medication is no longer effective or has become unsafe to use. Medical authorities state expired drugs are safe to take, even those that expired years ago.... Excluding nitroglycerin, insulin, and liquid antibiotics, most medications are as long-lasting as the ones tested by the military. Placing a medication in a cool place, such as a refrigerator, will help a drug remain potent for many years." *Drug Expiration Dates Do They Mean Anything?*, The Harvard Medical School Family Health Guide (November 2003 Update).
- 39. Johns Hopkins University has come to the same conclusion. Its web site, "Johns Hopkins Medicine Health Alerts," has reported that "expiration dates" are set very conservatively and are not the last date when drugs are effective:

Think of expiration dates – which the U.S. Food and Drug Administration (FDA) requires be placed on most prescription and OTC medications – as a very conservative guide to longevity. ... Most medications, though, retain their potency well beyond the expiration date, and outdated medications, whether prescription or OTC, are not usually harmful.

Johns Hopkins Health Alert, How Long Do Medications Last?, April 21, 2009.

40. Johns Hopkins also distinguished between drugs taken for serious diseases and OTC medications, like the ones at issue in this litigation, taken for a headache. The article advised that patients should consider replacing the former but not OTC drugs: "Also, consider replacing any outdated medications that you're taking for a serious health problem, since its

potency is more critical than that of an OTC drug you take for a headache or hay fever." *Id.* Contrary to that advice, Defendant tells consumers to throw away even OTC drugs.

41. In addition, the nursing profession is also aware that medications need not be discarded after the "expiration date" has passed. In 2008, Amy M. Karsh, associate professor of clinical nursing at the University of Rochester, stated in the American Journal of Nursing:

It seems reasonable to continue to use drugs past the stamped expiration date as long as caution is used with drugs that have a narrow therapeutic range, drugs in solution or suspension, nitroglycerin, tetracycline (Sumycin), and any drug that looks odd or develops a peculiar smell. (Aspirin, which is often stable for years after its expiration date, will start to smell like vinegar when it becomes unstable. It isn't toxic, but it will lack potency and should be discarded.)

Amy Karsh, *Waste Not?*, 108 Am. J. Nursing 86, 87 (2008). None of the types of drugs as to which she recommended using caution include Advil. *Id.*

- 42. Defendant's industry associations also acknowledge that OTC medications such as Advil remain effective long after their "expiration dates." PhRMA participates in, and CHPA is a supporter of, a campaign called "SMAR_xT DISPOSAL." The web site of this campaign states that "if stored properly, medications can remain effective (biologically active) for months or even years after the expiration date."⁵
 - C. Defendant deceptively tells consumers to throw away Advil after its so-called "expiration" date
- 43. Despite claiming to have an "ongoing commitment to transparency," Defendant misleads and deceives consumers into believing that supposedly expired Advil should be thrown away and that if it is not, it will be both unsafe and ineffective.
- 44. On its Advil web site, Defendant maintains a page entitled, "Medicine Cabinet Cleanout: Keep It Safe," which deceives consumers into believing that they are endangering

⁵ http://www.smarxtdisposal.net/questions.html (accessed October 11, 2012012).

themselves and their families if they don't get rid of supposedly expired medicines. On that page, Defendant states: "When was the last time you cleaned out your medicine cabinet? You may not even realize that you have unneeded, *expired* or recalled products. So it's time to take action—*protect your family* and clean it out!"

45. Pfizer also maintains a page of "Frequently Asked Questions," in which it deceptively states:

Can I use my bottle of Advil® beyond the expiration date?

It is not recommended to use the product past its expiration date as the effectiveness of the ingredients is only assured until the date printed on the package.⁷

- 46. Also contrary to Defendant's claim to be "focused ... on operating with transparency in everything we do," Defendant's Advil; web site omits the following material facts:
 - Defendant chooses the "expiration date" itself and chooses a date based on its own marketing considerations, not scientific reasons.
 - The product will remain safe after the "expiration date."
 - The "expiration date" does not indicate how long the product is actually "good" or safe to use.
 - The product will remain effective for long periods after the "expiration date" if stored properly.
 - Consumers may continue to take the product as long as it works as expected to relieve the consumers' symptoms and should discard it if it loses effectiveness.
 - To increase the life of the product, consumers should store it in a cool, dry place and not keep it in a hot and humid bathroom.

http://www.advil.com/medicine-cabinet-cleanout-keep-it-safe (accessed October 11, 2012) (emphasis added).
 http://www.advil.com/faqs?tid=16 (accessed October 11, 2012).

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47. In addition, every Pfizer over-the-counter medication sold in Missouri contains an "expiration date" but omits the information listed in the preceding paragraph, which is necessary to make that date not misleading.

- 48. Another way that Defendant carries out this scheme is through its industry associations, PhRMA and CHPA.
- 49. In the guise of protecting the environment, PhRMA's and CHPA's "SMAR_xT DISPOSAL" campaign encourages consumers to dispose of supposedly expired OTC medication. SMAR_xT DISPOSAL purports to provide consumers with "guidance on proper disposal of unused and *or expired* prescription and *OTC medications*." This web site preys upon consumers' desire to be good environmental stewards to encourage them to get rid of, not just unneeded medications, but supposedly expired medications that are still safe and effective.
- 50. As noted above, the **SMAR**_x**T DISPOSAL** campaign (and Defendant through its participation in it) admits that medications remain effective long after their "expiration dates." Yet, inexplicably the web site states that this is a reason to throw away these effective medicines rather than continuing to use them. Here is the complete question and answer containing this deceptive statement:

I have medicines in my cabinet that expired months, or even years, ago. Can I just dump those down the toilet?

The expiration date on medications is the date at which the manufacturer can still guarantee the safety and full potency of the medication. However, if stored properly, medications can remain effective (biologically active) for months or even years after the expiration date. Therefore, we also recommend you follow our SMAR_xT DISPOSAL guidelines for disposing of expired medicines. Important note: Never take an expired medication without checking with your pharmacist first.⁹

⁸ http://www.smarxtdisposal.net/questions.html (accessed October 11, 2012) (emphasis added).

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- 51. This statement is clearly designed to deceive consumers into discarding perfectly safe and effective OTC medications. If they were simply concerned about protecting the environment rather than increasing pharmaceutical sales, PhRMA, the CHPA, SMAR_xT DISPOSAL and Defendant would state on this web site and elsewhere that consumers could safely continue to take their supposedly expired OTC medications and not throw them away until they are no longer needed or effective.
- 52. PhRMA and CHPA also sponsor a campaign that purports to be designed to curb drug abuse, called "The American Medicine Chest Challenge." This program preys on consumers' desire to prevent drug abuse in order to persuade them to dispose of, not merely unneeded medications or drugs of abuse, but supposedly expired OTC medications.
- 53. On its web site, The American Medicine Chest Challenge invites consumers to "Take the American Medicine Chest Challenge ... in 5 Simple Steps." Two of those steps tell consumers that they should take an inventory of their OTC medicines and discard the ones that have supposedly "expired." Those two steps are:

Take inventory of your prescription and over-the-counter medicine.

* * *

Dispose of your unused, unwanted, and *expired* medicine in your <u>home</u> or at an American Medicine Chest Challenge Disposal site. ¹⁰

54. Moreover, CHPA maintains and makes publicly available on the internet a conduct code, called "Expiry Dating Code for OTC Drug Products," which states that the expiration date is "the date beyond which the drug product should not be used." In addition, the Code states "that consumers should, from time to time, review the contents of their OTC

¹⁰ http://www.americanmedicinechest.com/ (accessed October 11, 2012) (italic emphasis added).

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medicines [sic] inventory and discard products whose dates are past the expiration date fixed on the package."11

- 55. These various industry web sites omit the following material facts:
 - The manufacturer chooses the "expiration date" itself and chooses a date based on its own marketing considerations, not scientific reasons.
 - The product will remain safe after the "expiration date."
 - The "expiration date" does not indicate how long the product is actually "good" or safe to use.
 - The product will remain effective for long periods after the "expiration date" if stored properly.
 - Consumers may continue to take the product as long as it works as expected to relieve the consumers' symptoms and should discard it if it loses effectiveness.
 - To increase the life of the product, consumers should store it in a cool, dry place and not keep it in a hot and humid bathroom.
- 56. Defendant has no legitimate reason for misleading consumers about "expiration dates." Indeed, the reasons offered by the industry for not telling consumers that drugs remain safe and effective after they have supposedly expired or for failing to test them for longer periods do not hold up to analysis.
- 57. In an article published on December 18, 2006, on the website redorbit.com, Alan Goldhammer, vice-president of PhRMA, offered, as the only reason why drugs may not be effective after the "expiration date," that "[m]any consumers keep their drugs in the bathroom, exposed to heat and humidity that degrade drugs."

¹¹ Expiry Dating Code for OTC Drug Products, found at http://www.chpa-info.org/scienceregulatory/Voluntary Codes.aspx#expiry (accessed October 11, 2012).

¹² Study Highlights Debate Over Drug Expiration Dates, http://www.redorbit.com/news/health/771253/study highlights debate over drug expiration_dates/ (accessed October 11, 2012).

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- 58. This explanation was a sham as applied to Advil. On information and belief Defendant does not test its Advil products under high heat or humidity, and it does not advise consumers not to keep their medications in the bathroom.
- 59. Moreover, to the extent, if any, that it significantly degrades an OTC drug if it is kept in a hot and humid bathroom, such conditions occur before as well as after the "expiration date" and render the "expiration date" on the package inapplicable to a consumer's use of the product. This only adds to the reasons why Defendant's misrepresentations regarding its "expiration dates" are false and misleading.
- 60. Goldhammer also offered reasons why manufacturers do not test drugs for longer periods. Again his explanation was a sham. The article stated: "The industry calls the idea [of testing drugs for longer periods] a non-starter. Why would a company spend time and money testing a drug's shelf life when its patent expires after a number of years, Goldhammer said. Most medicines, he added, are given in quantities that should be taken fully to treat the illness, with no leftovers."
 - 61. Neither reason has any validity as applied to Advil.
 - Whatever the relevance of a product's patent protection is to a company's decision about shelf life, the issue does not apply to the drugs at issue here, which are not patented and which have generic equivalents on the market in the United States. Thus, there is no reason not to test the drugs for longer periods simply because they might come off patent.
 - The drugs at issue here are not sold in quantities limited to treat a single illness with no "leftovers." They are for recurring headaches, menstrual cramps, minor arthritis pains and the like. Defendant knows that. Otherwise there would be no reason to tell consumers to discard the drugs when they pass their "expiration dates."
- 62. Because of Defendant's actions, consumers do not know precisely, or even generally, how long Advil remains safe and effective. Thus, many consumers get rid of their Advil simply out of ignorance.

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CLASS ACTION ALLEGATIONS

63. Pursuant to Mo. Rev. Stat. § 407.025.3(6) and Missouri Rule of Civil Procedure 52.08(b)(2) with respect to the claim for injunctive and declaratory relief, and pursuant to Mo. Rev. Stat. § 407.025(7) and Missouri Rule of Civil Procedure 52.08(b)(3) with respect to the claim for actual damages, Plaintiff seeks to represent the following Class

All Missouri citizens who purchased Advil for personal, family, or household purposes and later discarded and replaced it.

Excluded from the proposed Class are Defendant, their Officers, Directors, and employees, as well as employees of any subsidiary, affiliate, successors, or assignees of Defendant. Also excluded is any trial judge who may preside over this case.

- 64. The Class is believed to comprise numerous consumers, the joinder of whom is impracticable, both because they are geographically dispersed across the state and because of their number.
- 65. Class treatment will provide substantial benefits to the parties and the Court. A well-defined commonality of interest in the questions of law and fact involved affect Plaintiff and the putative Class Members. Common questions of law and fact include:
 - a. What is the basis for the "expiration date" of Advil?
 - b. Is the "expiration date" of Advil the last date on which the medication is stable, safe and effective?
 - c. Is Advil safe after its "expiration dates?"
 - d. Is Advil effective after its "expiration dates?"
 - e. Does Defendant choose the "expiration dates" of Advil and does it choose dates based on marketing considerations, rather than scientific reasons?
 - f. Does Defendant advise consumers to discard their Advil after their "expiration dates?"
 - g. Does Defendant advise consumers that it is unsafe not to discard Advil after its "expiration date?"

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- h. Is it deceptive for Defendant to advise consumers to discard their Advil after its "expiration date?"
- i. Is it deceptive for Defendant not to advise consumers that it chooses the "expiration dates" of its Advil and chooses dates based on its own marketing considerations, not scientific reasons?
- j. Is it deceptive for Defendant not to advise consumers that their Advil will remain safe after the "expiration date?"
- k. Is it deceptive for Defendant not to advise consumers that their Advil will remain effective for long periods after the "expiration date?"
- 1. Is it deceptive for Defendant not to advise consumers that consumers may continue to take Advil as long as it remains effective and should discard it if it loses effectiveness?
- m. Is it deceptive for Defendant not to advise consumers that to increase the life of their Advil, they should store it in a cool, dry place and not keep it in a hot and humid bathroom?
- n. Is it an unfair practice under the MMPA for Defendant not to inform consumers how long Advil can be expected to remain safe and effective in the consumer's home?
- o. What relief is appropriate to remedy Defendant's illegal conduct described herein?
- 66. Questions of law and fact common to members of the Class, some of which are set forth above, predominate over any questions affecting only individual members of the Class. The resolution of common questions in this case will resolve the claims of both Plaintiff and the Class.
- 67. Plaintiff's claims are typical of the claims of the proposed Class in that Plaintiff and the members of the class purchased Advil for personal or household use and later discarded it after the "expiration date" and replaced the medication.
- 68. Plaintiff will fairly and adequately represent and protect the interests of the proposed Class. Plaintiff has no interests antagonistic to those of the Class. Plaintiff has retained competent and experienced counsel in the prosecution of this type of litigation.

- 69. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because members of the Class are numerous and individual joinder is impracticable. The expenses and burden of individual litigation would make it impracticable or impossible for proposed Class Members to prosecute their claims individually. Trial of Plaintiff's claims is manageable.
- 70. Unless a class is certified, Defendant will continue to engage in unfair and deceptive practices and continue to commit violations of Missouri law, to the detriment of Plaintiff and proposed Class Members.
- 71. Defendant has acted on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.
- 72. Plaintiff's claim for injunctive and declaratory relief on behalf of the Class is maintainable as a class action pursuant to Mo. Rev. Stat. § 407.025.3(6) and Missouri Rule of Civil Procedure 52.08(b)(2).
- 73. Plaintiff's claim for actual damages on behalf of the Class is maintainable as a class action pursuant to Mo. Rev. Stat. § 407.025(7) and Missouri Rule of Civil Procedure 52.08(b)(3).

JURY DEMAND

74. Plaintiff demands a trial by jury on all issues so triable.

COUNT I

VIOLATIONS OF THE MISSOURI MERCHANDISING PRACTICES ACT

75. Plaintiff incorporates by reference and re-alleges all preceding paragraphs of the Petition as though fully set forth herein.

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- 76. Defendant's web sites described herein, as well as the web sites maintained by its industry associations, as described herein, are advertisements as defined in the MMPA, Mo. Rev. Stat. § 407.010(1), because they are attempts by publication, dissemination, solicitation, circulation, or any other means to induce, directly or indirectly, consumers to enter or acquire any title or interest in any merchandise, specifically Advil.
- 77. Advil is merchandise as defined in the MMPA, Mo. Rev. Stat. § 407.010(4), because it is objects, wares or commodities.
- 78. Defendant is a person as that term is defined in the MMPA, Mo. Rev. Stat. § 407.010(4), because it is a for-profit corporation.
- 79. The sales by Defendant and the purchases by Plaintiff and the class members of Advil are sales as that term is defined in the MMPA, Mo. Rev. Stat. § 407.010(6), because they are sales of merchandise for cash or for credit.
- 80. The advertising, offering for sale and sale of the subject medications by Defendant, as described herein, constitute trade or commerce as defined in the MMPA, Mo. Rev. Stat. § 407.010(4), because they directly or indirectly affect the people of this state.
- 81. Defendant's actions described herein violate the MMPA in that they constitute deception, fraud, false pretense, false promise, misrepresentation, unfair practice and/or the concealment, suppression, or omission of material fact in connection with the sale of merchandise in trade or commerce, within the meaning of the MMPA.
- 82. Defendant's actions described herein violate the MMPA because they constitute unfair practices as that term is defined in Mo. Code Regs. tit. 15, § 60-8.020. Specifically, they (a) offend the public policy as it has been established by the Constitution, statutes or common law of this state, and/or by the Federal Trade Commission, and/or its interpretive decisions

and/or (b) are unethical, oppressive and/or unscrupulous. In addition, those actions present a risk of substantial injury to Plaintiff and the class, whose members are at risk of discarding safe and effective medication because of Defendant's actions as alleged herein.

- 83. Plaintiff purchased Advil manufactured by Defendant and thereby suffered an ascertainable loss of money or property as a result of the use or employment by Defendant of the actions described herein by virtue of having discarded that medication after its "expiration date" and spending money to replace it.
- 84. The unlawful actions of Defendant alleged herein caused similar injury to the other members of the Class.
- 85. Injunctive relief is necessary to protect Plaintiff and the members of the Class from Defendant's unlawful acts.

COUNT II – CIVIL CONSPIRACY

- 86. Plaintiff incorporates by reference and re-alleges all preceding paragraphs of the Petition as though fully set forth herein.
- 87. Defendant engages in a civil conspiracy to deceive consumers into discarding and replacing safe and effective medications that have passed its "expiration date" and to engage in the unfair practices described herein.
- 88. Defendant and the other members of PhRMA and CHPA are members of the conspiracy.
- 89. The conspiracy has the unlawful objective of deceiving consumers into believing that their supposedly expired OTC medications, including Advil, are neither safe nor effective, thereby inducing them to discard or stop using and replace them.

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- 90. Defendant and the other members of PhRMA and CHPA had a meeting of the minds on the object or course of the conspiracy. This meeting of the minds was and is manifested by the actions of those associations, as alleged herein.
 - 91. In furtherance of this conspiracy, Defendant committed the acts alleged herein.
- 92. The following actions of Defendant, among others, are unlawful overt acts in furtherance of the conspiracy.
 - The deceptive and unfair actions of Defendant, through PhRMA and CHPA, to mislead consumers into disposing of medications that had passed their "expiration dates," such as the "SMAR_xT DISPOSAL" and American Medicine Chest Challenge campaigns.
 - The deceptive and unfair statements and omissions of material facts on Defendant's web sites, as alleged herein.
 - The omission of material facts on the packaging of Defendant's OTC medications, as alleged herein.
- 93. Appropriate injunctive relief is necessary to undo the effects on Plaintiff and the Class of this civil conspiracy. If the civil conspiracy is not stopped by such injunctive relief, Plaintiffs and the members of the class will continue to suffer injury by being induced to discard safe and effective OTC medications and spending money for replacement medication.

PRAYER FOR RELIEF - ALL COUNTS

Plaintiff and Class request the Court enter judgment in their favor and against Defendant as follows:

(A) Ordering that this action be maintained as a class action on behalf of the following Class:

All Missouri citizens who purchased Advil for personal, family, or household purposes and who later discarded and replaced it.

Excluded from the class and subclasses are officers, directors and employees of Defendant and any entity affiliated with or controlled by

Defendant, counsel and members of the immediate families of counsel for Plaintiff herein, and the judge presiding over this action and any member of the judge's immediate family. Certifying Plaintiff as Class Representative and appointing Plaintiff's counsel as counsel for the Class;

- (B) Certifying Plaintiff as Class Representative and appointing Plaintiff's counsel as counsel for the Class;
- (C) Awarding appropriate equitable relief, as determined by the Court, including an order requiring Defendant to take all steps necessary to accurately disclose the meaning of the "expiration dates" printed on the packages of its Advil; to provide accurate information as to when its Advil products are no longer stable, safe, and effective; to tell consumers how to store their medications to extend the medications' useful lives; and to provide all applicable financial relief naturally flowing from Defendants' obligations under the injunction;
- (D) Awarding Plaintiff and the Class damages as provided by law;
- (E) Awarding Plaintiff and the Class punitive damages as provided by law;
- (F) Awarding Plaintiff and the Class costs and reasonable attorneys' fees herein;
- (G) Awarding such other and further relief as the court deems fit and proper.

Respectfully submitted,

LAW OFFICE OF RICHARD S. CORNFELD

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IN THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS STATE OF MISSOURI

MARJIE LEVY,

Plaintiff,

Case No.

Div.

Defendant.

CERTIFICATE OF SERVICE

The undersigned states that a true and correct copy of Plaintiff's First Request for Admissions Directed to Defendant Pfizer Inc.; Plaintiff's First Set of Interrogatories Directed to Defendant Pfizer Inc.; and Plaintiff's First Request for Production Directed to Defendant Pfizer Inc. was included with the Petition and Summons, to be served with them, on the following:

Pfizer Inc.

Serve: CT Corporation System 120 South Central Avenue Clayton, MO 63105 (314) 863-5545

Telas Copie

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I certify and attest that the above is a true copy of the original record of the Court in case number $\frac{|ZSL-CCb+DZO}{}$ as it appears on file in my office.



Issued

12-06-2012

JOAN M. GILMER, Circuit Clerk St. Louis County Circuit Court

Ву

Deputy Clerk